

Question Paper

Exam Date & Time: 09-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

END SEMESTER THEORY EXAMINATIONS- MAY 2018

PROGRAM: MPHARM SEMESTER 2

(PHARMACEUTICAL QUALITY ASSURANCE)

DATE: 09/05/2018

TIME: 2:00 PM - 5:00 PM

Pharmaceutical Manufacturing Technology [PQA-MQA204T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) Enlist and explain legal requirements and licences to set up API and formulation industry. (5)
- 2) Write a note on improved material handling. (5)
- 3) Write a note on film coating methods employed in tablet coating. (5)
- 4) Explain different types of closures and closure liners used in packaging. (5)
- 5) Write a note on principles of production planning. (5)
- 6) Write a note on design space and its significance in QbD. (5)
- 7) What is 'critical area' according to USFDA guidelines on aseptic processing? Explain in detail. (5)
- 8) Write a note on Process Automation of sterile semisolid preparations. (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) Define the terms production scheduling and routing. (2)
 - A)
 - B) Differentiate between at-line and in-line production control. (2)

- C) Differentiate between thermo plastic and thermos-set plastic (2)
- D) Differentiate between Type-I and Type-II glass. (2)
- E) Differentiate Clean in Place and Sterilization in Place. (2)

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